



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2012-N-0677]

Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the blade-form endosseous dental implant, a preamendments class III device, into class II (special controls). On its own initiative, based on new information, FDA is proposing to revise the classification of blade-form endosseous dental implants.

DATES: Submit either electronic or written comments on this proposed order by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section XI of this document for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0677, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0677 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert Docket No. FDA-2012-N-0677 into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), the Medical Devices Technical Corrections Act (Public Law 108-214) , the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III

and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act changing the process for reclassifying a preamendments device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon “new information.” FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term “new information,” as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland Rantos v. United States Department of Health, Education, and Welfare, 587 F.2d

1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see Bell v. Goddard, supra, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 389-391 (D.D.C. 1991)) or in light of changes in “medical science.” (See Upjohn v. Finch, supra, 422 F.2d at 951). Whether data before the Agency are past or new data, the “new information” to support reclassification under section 513(e) of the FD&C Act must be “valid scientific evidence,” as defined in section 513(a)(3) and 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Assoc. v. FDA, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).)

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must

occur: Publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b) of the FD&C Act; and consideration of comments to a public docket.

FDAMA added a new section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Device

On December 30, 1980 (45 FR 86025), FDA published a proposed rule for classification of endosseous dental implants (without distinguishing implants based on geometry) as class III requiring premarket approval. The panel recommended class III because the device is implanted in the body and presents a potential unreasonable risk of illness or injury including risks of abnormal spontaneous pain due to nerve impingement and a risk of perforation of the lingual and labial bony plates of the upper and lower jaws. On August 12, 1987 (52 FR 30082), a final rule was published for endosseous dental implants (again without distinguishing implants based on geometry) classifying these devices as class III. On December 7, 1989 (54 FR 50592), FDA published a proposed rule to require PMA submissions for all dental implants. A reclassification petition was subsequently submitted requesting reclassification of dental implants.

FDA held a reclassification panel meeting on October 24, 1991, and the panel voted to deny the reclassification petition. At the request of FDA, additional panel meetings were held on November 4, 1997, and January 13, 1998, during which FDA presented new information regarding root-form endosseous dental implants. During the January 1998 panel meeting, the panel stated that sufficient clinical information was presented to the panel to justify

reclassification of root-form implants, implants with special retention features, and temporary implants, as class II (special controls) requiring a 510(k) premarket notification. However, the panel also stated that sufficient evidence had not yet been presented to reclassify blade-form endosseous dental implants to class II.

On May 14, 2002 (67 FR 34416), and May 12, 2004 (69 FR 26302), proposed and final rules respectively were issued reclassifying only root-form implants into class II. Blade-form endosseous dental implant remained class III.

In 2009, FDA published an order under sections 515(i) and 519 of the FD&C Act (21 U.S.C. 360i) for the submission of information on blade-form endosseous dental implants (74 FR 16214, April 9, 2009). In response to that order, FDA received information from one device manufacturer; however, the information was related to other types of dental implants and was not relevant for this proposed rule.

III. Device Description

The blade-form endosseous dental implant is a device placed into the maxilla or mandible and composed of biocompatible material, such as titanium alloy or commercially pure (c.p.) titanium, with sufficient strength to support a dental restoration, such as a crown, bridge, or denture, intended for the purpose of replacing tooth (or teeth) roots and extending a support post through the gingival tissue into the oral cavity to restore chewing function. The blade-form implants are either one-piece or two-piece implants designed with one to three cylindrical abutment posts extending from the coronal aspect of the blade through the soft tissue and into the oral cavity. For the two-piece design, the separate abutment post is retained to the blade implant with a screw.

The blade-form implant is generally a rectangular shape or rounded corner rectangle shape (in the mesio-distal plane) with a narrow tapered (narrow at the apical edge) edge (in the bucco-lingual plane) similar in shape to a razor blade. Other blade designs, such as square, V-shaped, and triangles have also been used. The blade generally contains open vents of various shapes and various sizes.

IV. Proposed Reclassification

FDA is proposing that the device subject to this proposal be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls applicable to the devices, would provide reasonable assurance of their safety and effectiveness. FDA believes that the identified special controls in this proposed order, if finalized, together with general controls applicable to the device, would provide reasonable assurance of safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and 21 CFR 860.130, based on new information with respect to the devices and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in the next section, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for blade-form endosseous dental implant devices.

FDA has also considered blade-form endosseous dental implant devices in accordance with the reserved criteria set forth in section 513(a) of the FD&C Act and decided that the device does require premarket notification. The Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as allowed under section 510(m) of the FD&C Act.

V. Risks to Health

After considering available information, including the recommendations of the advisory committees (panels) for the classification of these devices, FDA has evaluated the risks to health associated with the use of blade-form endosseous dental implant devices and determined that the following risks to health are associated with its use:

- Local tissue or existing dentition degeneration: Localized tissue and existing dentition degeneration may be caused by endosseous implants due to excessive mobility, loss of integration, incompatibility of device components, or structural failure of the device.
- Pain: Nerve impingement by the device may cause pain.
- Bone or nerve damage: Improper design or use of the device may cause injury during surgery related to sinus perforation, alveolar plate perforation, or nerve damage resulting in transient or chronic pain/facial nerve paresis.
- Infection: Implantable devices may introduce microorganisms that may cause local or systemic infections.
- Adverse tissue reaction: Inadequate tissue compatibility of the materials used in this device could cause an immune reaction.

- Migration or thermal injury: Incompatibility with magnetic resonance imaging may cause the device to migrate or heat.

VI. Summary of Reasons for Reclassification

If properly manufactured and used, blade-form endosseous dental implants can help restore the patient's chewing function by replacing tooth roots and extending a support post through the gingival tissue into the oral cavity in order to support a dental restoration, such as a crown, bridge, or denture. FDA believes that blade-form endosseous dental implant devices should be reclassified into class II because special controls, together with general controls, can be established to provide reasonable assurance of the safety and effectiveness of the device, and because general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. In addition, there is now adequate effectiveness information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

Since the time of the panel recommendation, sufficient evidence has been developed to support a reclassification of blade-form endosseous dental implants to class II with special controls. FDA has been reviewing these devices for many years and their risks are well known. A review of the applicable clinical literature indicates that the device has a high success rate (remaining implanted/not removed) and that few relevant adverse events have been reported in the case of these devices or related devices suggesting that the device has a high long-term safety profile. FDA believes that the special controls identified in this proposed order, if finalized, together with general controls, can provide a reasonable assurance of the safety and effectiveness of blade-form endosseous dental implants.

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are sufficient to mitigate the risks to health described in section V of this document:

- The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use;
- Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;
- Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;
- The device must be demonstrated to be biocompatible;
- Sterility testing must demonstrate the sterility of the device;
- Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;
- Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, and relevant precautions and warnings based on the clinical use of the device;
- Patient labeling must contain a description of how the devices works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and

- Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Blade-form endosseous dental implants are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed 21 CFR 872.3640(a); see section 520(e) of the FD&C Act and 21 CFR 801.109 (Prescription devices)). Prescription-use restrictions are a type of general controls authorized under section 520(e) of the FD&C Act and defined as a general control in section 513(a)(1)(A)(i) of the FD&C Act; and under 21 CFR 807.81, the device would continue to be subject to 510(k) notification requirements.

IX. Environmental Impact

The Agency has determined under 21 CFR 25.34(b)) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

XI. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the Federal Register or at a later date if stated in the final order.

XII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872--DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.3640 is amended by revising paragraphs (a) and (b)(2) to read as follows:

§ 872.3640 Endosseous dental implant.

(a) Identification. An endosseous dental implant is a prescription device made of a material such as titanium or titanium alloy that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) * * *

(2) Class II (special controls). The device is classified as class II if it is a blade-form endosseous dental implant. The special controls for this device are:

(i) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use;

(ii) Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;

(iii) Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;

(iv) The device must be demonstrated to be biocompatible;

(v) Sterility testing must demonstrate the sterility of the device;

(vi) Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;

(vii) Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, and relevant precautions and warnings based on the clinical use of the device;

(viii) Patient labeling must contain a description of how the devices works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and

(ix) Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Dated: January 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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